



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/892,993	06/27/2001	Kelly R. Brown	ETH-1567	3764

27614 7590 07/13/2005

MCCARTER & ENGLISH, LLP  
FOUR GATEWAY CENTER  
100 MULBERRY STREET  
NEWARK, NJ 07102

EXAMINER

FUBARA, BLESSING M

ART UNIT	PAPER NUMBER
----------	--------------

1618

DATE MAILED: 07/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/892,993	<b>Applicant(s)</b> BROWN ET AL.	
	<b>Examiner</b> Blessing M. Fubara	<b>Art Unit</b> 1618	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 15 April 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-4 and 6-28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 6-25 is/are rejected.
- 7) ☒ Claim(s) 26-28 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Examiner acknowledges receipt of request for extension of time and request for continued examination filed 03/07/05, compliant amendment and remarks filed 04/15/05 and 03/07/05 respectively. Claims 1-4 and 6-28 are pending.

#### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicants' submission filed on 03/07/05 has been entered.

#### ***Claim Rejections - 35 USC § 102***

1. Claims 1-4, 6-17, 23 and 24 remain rejected under 35 U.S.C. 102(e) as being anticipated by Vyakarnam et al. (US 6,333,029).

Applicants' argument that Vyakarnam does not disclose interaction between the polymer phase and the ceramic phase and that there is no interphase zone is not persuasive because Vyakarnam discloses that the foam could be reinforced with ceramic fibers or particles (column 6, lines 27-29), the pores of the foam may be partially or completely filled with ceramic materials (column 17, lines 31, 32 and 34; claims 21, 42 and 63) and the interphase zone broadly reads on point where the ceramic makes contact with the foam pores.

***Claim Rejections - 35 USC § 103***

2. The rejection of claims 1-4 and 6-24 under 35 U.S.C. 103(a) as being unpatentable over Tormala et al. (US 5,084,051) in view of Vyakarnam et al. (US 6,333,029) is withdrawn because applicants' argument is persuasive that the signed statement of common ownership removes the Vyakarnam reference as art under 35 USC 103.

3. The rejection of claims 18-22 and 25-28 rejected under 35 U.S.C. 103(a) as being unpatentable over Vyakarnam et al. (US 6,333,029) is withdrawn because applicants' argument is persuasive that the signed statement of common ownership removes the Vyakarnam reference as art under 35 USC 103.

4. Claims 1-4 and 6-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tormala et al. (US 5,084,051) in view of Shalaby et al. (US 5,847,012) or Wallajapet et al. (US 5,948,829).

Tormala discloses a biocomposite material that comprises at least partially porous bioceramic component and porous material component where the material component comprises resorbable polymer selected from the group consisting of polymer, copolymer, polymer mixture and ceramic materials and mixtures thereof (abstract, column 5, lines 9-64, column 6, lines 12-40 and claims 1 and 2). Specific polymers are polyglycolic acid, polylactic acid and others lists in Table 1 and claim 2 and these polymers are biodegradable. The bioceramic component and the polymer material component are mechanically reinforced with fibers (column 9, lines 1-10). The bioceramic component is composed of materials selected from calcium phosphate, fluoroapatite, calcium carbonate, magnesium calcium phosphate, bioglasses, glass ceramics or mixtures of ceramics (column 6, lines 41-46 and claim 4). In column 11, lines 2-14, Tormala

Art Unit: 1618

discloses that the material component penetrates at least somewhat into the pores of the bioceramic during the manufacturing process of the biocomposite. The polymer component can be reinforced with fabric or with parallel or randomly oriented fibers and the reinforcement material can be made of resorbable materials such as polymer, copolymer, polymer mixture and/or ceramic material (column 8, lines 57-67 and column 9, lines 45-52).

Regarding claim 8, reinforcement structure could be any polymer disclosed in Tormala. In this regard, it may be noted that Tormala in column 9, lines 45-50 discusses that the reinforcement material can be any of the polymer disclosed in Tables 1 and 2 and also in example 4, PGA/PLLA fiber fabric is the reinforcement material. Thus the PGA/PLLA can be substituted for by any of the other polymers including poly-dioxanone (PDS) with the expectation of achieving the desired reinforcement. Regarding the amounts of each of the polymers in the mixed polymer component, it is within the purview of the person of skill or ordinary skill in the art to use appropriate amounts of each of the polymer in the mixed polymer component with the expectation of providing desired mechanical properties.

Tormala discloses the biocomposite material of the instant claims but fails to specifically state that the polymer composite material is a foam. Nonetheless, Tormala discloses drying the composite material and the solvent is evaporated under vacuum (column 19, 5, 17 and 27). Shalaby discloses that freeze drying (or lyophilization) and salt leaching are two traditional techniques for producing foam (column 2, lines 23, 24 and 32-34). Wallajapet discloses that foams can be formed by freeze drying (column 2, lines 49-55).

Since lyophilization or freeze drying is an alternate drying process, it would have been obvious to one of ordinary skill in the art at the time the invention was made to dry the

Art Unit: 1618

biocomposite material of Tormala under normal conditions or under vacuum. One having ordinary skill in the art would have been motivated to freeze dry or lyophilize the biocomposite material of Tormala with the expectation that, substituting lyophilization for drying under vacuum or drying without vacuum would produce a composite that is a foam since lyophilizing produces a foam according to Shalaby and Wallajapet.

5. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. White et al. (US 6,376,573) discloses a porous ceramic material "in which a polymer such as polylactic acid is polymerized in situ to fill the micropores substantially without filling the macropores" (abstract; column 2, line 64 to column 3 line 38; column 4, lines 38-63). White is silent on the porosity of the polyester polymer infiltrating or coating or filling the micropores of the porous ceramic.

6. Claims 26-28 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1618

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Blessing Fubara  
Patent Examiner  
Tech. Center 1600

A handwritten signature in black ink, appearing to read "Blessing Fubara", is written over the printed name.